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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,546	03/12/2002	Hiroshi Tanaka	YAM2 0010	9731

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Richard M Klein  
Fay Sharpe Fagan Minnich & McKee  
1100 Superior Avenue Seventh Floor  
Cleveland, OH 44114

EXAMINER
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HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/914,546

Applicant(s)

TANAKA ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 28 August 2003, and of supplemental Response, dated 6 October 2003.
2. Applicant has amended claims 1-5. New claims 6-19 have been added. Claims 1-19 are pending, and are examined in the instant action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. It is noted that Applicant has included reference articles with this Response (p. 9). However, a proper submission of references must comply with 37 CFR 1.97 and include a filled-out PTO 1449 for consideration by the Office.

***Drawings***

7. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the evidence as described in the specification. Figure 3 is of such poor quality that the Examiner is unable to evaluate the data the Figure is cited as representing. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
8. Applicant's Petition to accept color photographs has been accepted.

***Claim Rejections - 35 USC § 112-second***

9. Claims 1-19 are rejected under 35 U.S.C. 112-2<sup>nd</sup>. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

In claim 1, line 6, "selecting the seed with the DNA of interest"—"with" is ambiguous, because the term can mean either "using" or "containing".

In claim 10, "the callus" lacks antecedent basis.

In claim 14, "a selection marker" is unclear. Is this a chemical? Or some conditional change?

In claim 18, line 3, "a plant regulatory substance" is unclear. Is this a nutritional supplement? Or a plant growth regulator?

***Claim Rejections - 35 USC § 112-New Matter***

10. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The phrases "preculturing the intact seed", "selecting the seed", "allowing the selected seed to produce a transformed monocotyledonous plant" and "callus" are not supported by the originally filed specification or claims. Applicant is invited to point out the page and line number in the specification where support for these phrases can be

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found. Absent such support, Applicant is required to cancel the new matter in response to this Office Action.

***Claim Rejections - 35 USC § 112-Enablement***

11. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method for a transformation of a rice plant by (i) preculturing rice seeds on N6D medium containing 2,4-D (2 mg/L) and sucrose (30 g/L) for 5 days at 27-32C, (ii) Agrobacterium infection by immersing precultured seed in a suspension of Agrobacterium bearing pGHIHm plasmid, and incubating in the dark at 28C for three days, followed by elimination of Agrobacterium using carbenicillin, (iii) selection by placing the seeds on ND6 medium containing 2, 4-D (2 mg/liter), plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating at 27C for 7 more days, (iv) a second selection, by placing the seeds on ND6 medium containing 2, 4-D, 2 —4 mg/liter, plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating 27C for 7 more days, (v) regenerating plants using regeneration medium as described; is not enabling for a method of transforming any monocot comprising unspecified conditions which do not contain specific concentrations, specific time durations, light conditions and temperature conditions, throughout the broad scope of the claims.

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Applicant provides a single working example, with detailed information about protocol, and results in the specification. This example is a method (specification, Example I, pages 16-19), for the transformation of a rice plant by (i) preculturing rice seeds on N6D medium containing 2,4-D and sucrose for 5 days at 27-32C (as described in Section 1.1, specification, page 16), (ii) Agrobacterium infection by immersing precultured seed in a suspension of Agrobacterium bearing pGHIHm plasmid, and incubating in the dark at 28C for three days, (as described in Section 1.3, p 17), followed by elimination of Agrobacterium using carbenicillin, (as described in Section 1.4, p 17), (iii) selection (as described in Section 1.4, pages 17-18), by placing the seeds on ND6 medium containing 2, 4-D, 2 mg/liter, plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating at 27C for 7 more days, (iv) a second selection (as described in Section 1.4, page 18), by placing the seeds on ND6 medium containing 2, 4-D, 2 –4 mg/liter, plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating 27C for 7 more days, (v) regenerating plants using regeneration medium as described (as described in Section 1.5, pages 18-19). Applicant has not taught other transformation conditions. While the specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable*, and must be recited in the claims. Applicant provides no guidance for pre-treatment conditions, the infection conditions for the Agrobacterium, the selection agent and conditions for selection. For the claimed method to be enabled, guidance must be given for both the concentrations and the duration of the treatment periods. Testing the parameters of concentration, temperature, light conditions and

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duration times would require a myriad of experiments, comprising an infinite number of combinations of variables. In the absence of such guidance, Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

### Remarks

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00. *Note that Examiner's phone number will change to 571-272-0796 as of 6 January 2004.*

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.



Georgia Helmer PhD  
Patent Examiner  
Art Group 1638  
December 26, 2003

AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600